Liza M. Walsh
Rukhsanah L. Singh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
Phone: (973) 535-0500
Fax: (973) 535-9217

Of Counsel:
Ralph J. Gabric (*pro hac vice pending*)
Joshua E. Ney, Ph.D. (*pro hac vice pending*)
Danielle C. Gillen (*pro hac vice pending*)
David M. Hanna (*pro hac vice pending*)
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive, Suite 3600
Chicago, Illinois 60611-5599
Phone: (312) 321-4200

Attorneys for Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Andrx Corp., and Actavis Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVEN THERAPEUTICS, LLC, Plaintiff, v. ACTAVIS LABORATORIES FL, INC., ACTAVIS PHARMA, INC., ANDRX CORP., and ACTAVIS, INC., Defendants.	Civil Action No. 2:14-cv-06414 (FSH-MAH) Judge Faith S. Hochberg Magistrate Judge Michael A. Hammer ***Document Electronically Filed***

DEFENDANTS' ANSWER AND DEFENSES TO COMPLAINT FOR PATENT INFRINGEMENT, DEFENDANT ACTAVIS LABORATORIES FL, INC.'S COUNTERCLAIMS, AND DEFENDANTS' DEMAND FOR JURY TRIAL

Defendants Actavis Laboratories FL, Inc. ("ALF"), Actavis Pharma, Inc. ("Actavis Pharma"), Andrx Corporation ("Andrx"), and Actavis, Inc. ("Actavis") (collectively, "Defendants") hereby file their Answer and Defenses and ALF's Counterclaims, in response to the Complaint for Patent Infringement of Noven Therapeutics, LLC ("Noven" or "Plaintiff").

THE PARTIES

1. Noven is a Delaware limited liability company with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

RESPONSE:

Defendants are without knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 1 and therefore deny them.

2. Upon information and belief, defendant Actavis Laboratories FL, Inc. is a Florida corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

RESPONSE:

Defendants admit that ALF is a Florida corporation. Defendants deny the remaining allegations of Paragraph 2.

3. Upon information and belief, defendant Actavis Laboratories FL, Inc. is in the business of preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the state of New Jersey.

RESPONSE:

Defendants admit that ALF is engaged in the development and manufacturing of pharmaceutical products. Defendants deny the remaining allegations of Paragraph 3.

4. Upon information and belief, defendant Actavis Pharma, Inc. is a Delaware corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

RESPONSE:

Defendants admit that Actavis Pharma is a Delaware corporation with a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Defendants deny the remaining allegations of Paragraph 4.

5. Upon information and belief, defendant Actavis Pharma, Inc. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

RESPONSE:

Defendants admit that Actavis Pharma is engaged in the marketing and distribution of pharmaceutical products. Defendants deny the remaining allegations of Paragraph 5.

6. Upon information and belief, defendant Andrx Corp. is a Delaware corporation with a principal place of business at 4955 Orange Drive, Davie, FL 33314.

RESPONSE:

Defendants admit that Andrx is a Delaware corporation with a place of business at 4955 Orange Drive, Davie, FL 33314. Defendants deny the remaining allegations of Paragraph 6.

7. Upon information and belief, defendant Andrx Corp. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

RESPONSE:

Defendants admit that Andrx is engaged in the marketing and distribution of pharmaceutical products. Defendants deny the remaining allegations of Paragraph 7.

8. Upon information and belief, defendant Actavis, Inc. is a Nevada corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

RESPONSE:

Defendants admit that Actavis is a Nevada corporation with a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Defendants deny the remaining allegations of Paragraph 8.

9. Upon information and belief, defendant Actavis, Inc. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

RESPONSE:

Defendants admit that Actavis is engaged in the marketing and distribution of pharmaceutical products. Defendants deny the remaining allegations of Paragraph 9.

10. Upon information and belief, defendant Actavis Laboratories FL, Inc. is a wholly-owned subsidiary of defendant Andrx Corp. In turn, upon information and belief, defendants Andrx Corp. and Actavis Pharma, Inc. are wholly-owned subsidiaries of defendant Actavis, Inc.

RESPONSE:

Admitted.

NATURE OF THE ACTION

11. This is a civil action for patent infringement of U.S. Patent Nos. 5,874,447 (the "'447 patent"), 7,598,271 (the ''271 patent"), and 8,658,663 (the ''663 patent") (collectively, the "patents-in-suit"), arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq*., and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 207139, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of Noven's BRISDELLE® product, which is sold in the United States.

RESPONSE:

Defendants admit that Plaintiff's Complaint purports to be an action for alleged patent infringement of U.S. Patent Nos. 5,874,447 (the "'447 patent"), 7,598,271 (the ''271 patent"), and 8,658,663 (the ''663 patent") (collectively, the "patents-in-suit"), arising under the patent laws of the United States, Title 35, United States Code § 100, *et. seq*., including under 35 U.S.C. § 271. Defendants admit that this action relates to the submission of Abbreviated New

Drug Application ("ANDA") No. 207139 by ALF to the United States and Food Drug Administration ("FDA") seeking approval to engage in the manufacture, use or sale of a generic version of BRISDELLE® (paroxetine mesylate) Capsules. Defendants deny the remaining allegations of Paragraph 11.

JURISDICTION AND VENUE

12. This is a civil action for patent infringement and declaratory judgment arising under the Patent Laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

RESPONSE:

Defendants admit that Plaintiff's Complaint purports to be an action for alleged patent infringement and declaratory judgment arising under 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendants deny the remaining allegations of Paragraph 12.

13. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE:

ALF admits that this Court has subject matter jurisdiction over the claims asserted against ALF under 28 U.S.C. §§ 1331 and 1338(a). Actavis Pharma, Andrx, and Actavis deny that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a) over the claims asserted against them; however, in the interest of efficiency and expediting litigation on the merits, Actavis Pharma, Andrx, and Actavis hereby answer the Complaint. For the remaining allegations of this paragraph, no response is required at this time because these allegations are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the remaining allegations of Paragraph 13.

14. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their systematic and continuous contacts with, the State of New Jersey.

RESPONSE:

For purposes of this action only, Defendants do not contest personal jurisdiction.

Defendants deny the allegations of Paragraph 14.

15. Upon information and belief, Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc. have their principal place of business in Parsippany, New Jersey.

RESPONSE:

Denied.

16. Upon information and belief, Defendants are registered to do business in the state of New Jersey, and purposefully avail themselves of this forum by making, using, importing, selling or offering to sell pharmaceutical products in the state of New Jersey, or causing others to do the same, and therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts.

RESPONSE:

Defendants admit that Actavis Pharma and Actavis are registered to do business in the state of New Jersey and each have a registered agent there. Defendants deny the remaining allegations of Paragraph 16.

17. Upon information and belief, Actavis, Inc., the parent company of the other Defendants in this matter, holds a current and valid New Jersey "Wholesale Drug & Medical Devices" registration, No. 5003854.

RESPONSE:

Admitted that Actavis, Inc. holds a current and valid New Jersey "Wholesale Drug & Medical Devices" registration, No. 5003854. Defendants deny the remaining allegations of Paragraph 17.

18. Upon information and belief, Defendants collectively share common directors, officers, and facilities, operate as agents of each other, and act in concert in the design, development, manufacture, distribution, and sale of pharmaceutical products throughout the United States, including New Jersey.

RESPONSE:

Denied.

19. Upon information and belief, Defendants collectively participated in the preparation, development and filing of ANDA No. 207139 and its underlying subject matter, which occurred in the state of New Jersey.

RESPONSE:

Denied.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

RESPONSE:

For purposes of this action only, Defendants do not contest venue. Defendants deny the allegations of Paragraph 20.

FACTUAL BACKGROUND

21. The '447 patent, entitled "4-Phenylpiperidine Compounds for Treating Depression," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 23, 1999. Noven is the owner of all title, right, and interest in and to the '447 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '447 patent is attached as Exhibit A.

RESPONSE:

Defendants admit that a purported copy of the '447 patent, entitled "4-Phenylpiperidine Compounds for Treating Depression," is attached to the Complaint as Exhibit A, and purportedly was issued by the United States Patent and Trademark Office ("USPTO") on February 23, 1999. Defendants deny that the' 447 patent was "duly and legally issued." Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21 and therefore deny them.

22. The '271 patent, entitled "Crystalline Paroxetine Methane Sulfonate," was duly and legally issued by the USPTO on October 6, 2009 and a certificate of correction was issued on May 17, 2011. Noven is the owner of all title, right, and interest in and to the '271 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '271 patent and certificate of correction is attached as Exhibit B.

RESPONSE:

Defendants admit that a purported copy of the '271 patent, entitled "Crystalline Paroxetine Methane Sulfonate," is attached to the Complaint as Exhibit B, and was purportedly issued by the USPTO on October 6, 2009. Defendants also admit that a purported copy of a certificate of correction for the '271 patent is attached to the Complaint as Exhibit B, and was purportedly issued by the USPTO on May 17, 2011. Defendants deny that the '271 patent was "duly and legally issued." Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 and therefore deny them.

23. The '663 patent, entitled "Method of Treating Thermoregulatory Dysfunction With Paroxetine," was duly and legally issued by the USPTO on February 25, 2014 and a certificate of correction was issued on October 7, 2014. Noven is the owner of all title, right, and interest in and to the '663 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '663 patent and certificate of correction is attached as Exhibit C.

RESPONSE:

Defendants admit that a purported copy of the '663 patent, entitled "Method of Treating Thermoregulatory Dysfunction With Paroxetine," is attached to the Complaint as Exhibit C, and was purportedly issued by the USPTO on February 25, 2014. Defendants also admit that a purported copy of a certificate of correction for the '663 patent is attached to the Complaint as Exhibit C, and was purportedly issued by the USPTO on October 7, 2014. Defendants deny that the '663 patent was "duly and legally issued." Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 23 and therefore deny them.

24. Noven is the holder of New Drug Application ("NDA") No. 204516 for the manufacture and sale of paroxetine mesylate capsules, which Noven markets and sells under the registered trademark BRISDELLE®. Pursuant to Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) ("FFD&C Act") and corresponding FDA regulations, Noven has listed the

patents-in-suit in the FDA's Orange Book as covering the BRISDELLE® drug and methods for using it.

RESPONSE:

Defendants admit that Noven is the apparent holder of New Drug Application ("NDA") No. 204516 for BRISDELLE® (paroxetine mesylate) Capsules. Defendants admit that the patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") with respect to BRISDELLE® (paroxetine mesylate) Capsules. The requirements of 21 U.S.C. § 355(b)(1) speak for themselves. Defendants deny the remaining allegations of Paragraph 24.

25. Upon information and belief, pursuant to FFD&C Act 21 U.S.C. § 505(j), Defendants filed ANDA No. 207139 with the FDA. Defendants' ANDA seeks FDA approval to market and sell within the United States a generic 7.5 mg paroxetine mesylate capsule product (the "generic product") prior to the expiration of the patents-in-suit.

RESPONSE:

Defendants admit that ALF filed ANDA No. 207139 with the FDA, according to applicable laws and regulations, seeking approval to engage in the commercial manufacture, use or sale of 7.5 mg paroxetine mesylate capsules before the expiration of the patents-in-suit. The requirements of 21 U.S.C. § 505(j) speak for themselves. Defendants deny the remaining allegations of Paragraph 25.

26. Upon information and belief, Defendants' ANDA No. 207139 identified Noven's BRISDELLE® product and included a written certification, as required by FFD&C Act 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the patents-in-suit are invalid or otherwise will not be infringed by Defendants' generic product.

RESPONSE:

Defendants admit that ALF included a written certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in ALF's opinion and to the best of its knowledge the claims of the patents-in-suit are invalid, unenforceable, and/or will not

be infringed by the commercial manufacture, use or sale of the drug products described in ANDA No. 207139 (hereinafter, "ALF ANDA Product"). Defendants also admit that ALF identified BRISDELLE® as the reference listed drug product in ANDA No. 207139. Defendants deny the remaining allegations of Paragraph 26.

27. On or about September 4, 2014, Noven received a letter from Defendants purporting to be a written notice that Defendants have filed ANDA No. 207139 prior to the expiration of the patents-in-suit, pursuant to FFD&C Act 21 U.S.C. § 505(j)(2)(B)(iv) (the "Paragraph IV letter"). The Paragraph IV letter included notice of Defendants' allegations that the patents-in-suit are invalid, unenforceable and/or not infringed by Defendants' generic product.

RESPONSE:

Defendants admit that by a letter dated September 3, 2014, ALF provided Noven with written notification that ALF filed ANDA No. 207139, which contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the ALF ANDA Product before the expiration of the patents-in-suit ("ALF Notice Letter"). Defendants also admit that the ALF Notice Letter included written notice that in ALF's opinion and to the best of its knowledge the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the ALF ANDA Product. Defendants are without knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 27 and therefore deny them.

28. Defendants' submission of ANDA No. 207139, including the Paragraph IV certification, to the FDA constitutes infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2). Moreover, Defendants' anticipated commercial manufacture, use, sale, offer for sale, or importation of the generic product will infringe the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

RESPONSE:

Defendants admit that it is a technical act of patent infringement under 35 U.S.C. § 271(e)(2) to submit an application under 21 U.S.C. § 355(j) for a drug claimed in a

patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under the United States Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. For the remaining allegations of this paragraph, no response is required at this time because these allegations are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the remaining allegations of Paragraph 28.

29. Noven commenced this action within 45 days of receiving Defendants' Paragraph IV letter.

RESPONSE:

Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29 and therefore deny them.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,874,447

30. Paragraphs 1-29 are incorporated by reference as though fully set forth herein.

RESPONSE:

Defendants incorporate and reallege its responses to Paragraphs 1 through 29 above, as if set forth in full herein.

31. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '447 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

RESPONSE:

Defendants admit that it is a technical act of infringement under 35 U.S.C. § 271(e)(2) to submit an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such admission is to obtain approval under the United States Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for

sale, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. Defendants deny the remaining allegations of Paragraph 31.

32. Upon information and belief, Defendants will infringe the '447 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 32.

33. Upon information and belief, Defendants will induce infringement of the '447 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '447 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 33.

34. Upon information and belief, Defendants will contributorily infringe the '447 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '447 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 34.

35. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably

harmed if Defendants' direct, induced, and contributory infringement of the '447 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

RESPONSE:

Denied.

36. Upon information and belief, Defendants were aware of the '447 patent prior to filing ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '447 patent.

RESPONSE:

Defendants admit that ALF was aware of the existence of the '447 patent when it filed ANDA No. 207139 with a Paragraph IV Certification. Defendants deny the remaining allegations of Paragraph 36.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,874,447

37. Paragraphs 1-36 are incorporated by reference as though fully set forth herein.

RESPONSE:

Defendants incorporate and reallege its responses to Paragraphs 1 through 36 above, as if set forth in full herein.

38. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 38.

39. There is an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 39.

40. Defendants have made, and will continue to make, substantial preparation in the United States, including New Jersey, to manufacture, use, sell, offer to sell, or import the generic product upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of paragraph 40.

41. Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '447 patent will constitute direct, induced, and contributory infringement of said patent.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 41.

42. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '447 patent will constitute direct, induced, and contributory infringement of the '447 patent.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 42.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,598,271

43. Paragraphs 1-42 are incorporated by reference as though fully set forth herein.

RESPONSE:

Defendants incorporate and reallege its responses to Paragraphs 1 through 42 above, as if set forth in full herein.

44. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '271 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

RESPONSE:

Defendants admit that it is a technical act of infringement under 35 U.S.C. § 271(e)(2) to submit an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such admission is to obtain approval under the United States Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. Defendants deny the remaining allegations of Paragraph 44.

45. Upon information and belief, Defendants will infringe the '271 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 45.

46. Upon information and belief, Defendants will induce infringement of the '271 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '271 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 46.

47. Upon information and belief, Defendants will contributorily infringe the '271 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '271 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 47.

48. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '271 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

RESPONSE:

Denied.

49. Upon information and belief, Defendants were aware of the '271 patent prior to filing ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '271 patent.

RESPONSE:

Defendants admit that ALF was aware of the existence of the '271 patent when it filed ANDA No. 207139 with a Paragraph IV Certification. Defendants deny the remaining allegations of Paragraph 49.

COUNT IV: DECLARATORY JUDGMENT
OF INFRINGEMENT OF U.S. PATENT NO. 7,598,271

50. Paragraphs 1-49 are incorporated by reference as though fully set forth herein.

RESPONSE:

Defendants incorporate and reallege its responses to Paragraphs 1 through 49 above, as if set forth in full herein.

51. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 51.

52. There is an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 52.

53. Defendants have made, and will continue to make, substantial preparation in the United States, including New Jersey, to manufacture, use, sell, offer to sell, or import the generic product upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 53.

54. Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '271 patent will constitute direct, induced, and contributory infringement of said patent.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 54.

55. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '271 patent will constitute direct, induced, and contributory infringement of the '271 patent.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 55.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,658,663

56. Paragraphs 1-55 are incorporated by reference as though fully set forth herein.

RESPONSE:

Defendants incorporate and reallege its responses to Paragraphs 1 through 55 above, as if set forth in full herein.

57. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '663 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

RESPONSE:

Defendants admit that it is a technical act of infringement under 35 U.S.C. § 271(e)(2) to submit an application under 21 U.S.C. § 355(j) for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such admission is to obtain approval under the United

States Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. Defendants deny the remaining allegations of Paragraph 57.

58. Upon information and belief, Defendants will infringe the '663 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 58.

59. Upon information and belief, Defendants will induce infringement of the '663 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '663 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 59.

60. Upon information and belief, Defendants will contributorily infringe the '663 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '663 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 60.

6l. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '663 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

RESPONSE:

Denied.

62. Upon information and belief, Defendants were aware of the '663 patent prior to filing ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '663 patent.

RESPONSE:

Defendants admit that ALF was aware of the existence of the '663 patent when it filed ANDA No. 207139 with a Paragraph VI Certification. Defendants deny the remaining allegations of Paragraph 62.

COUNT VI: DECLARATORY JUDGMENT
OF INFRINGEMENT OF U.S. PATENT NO. 8,658,663

63. Paragraphs 1-62 are incorporated by reference as though fully set forth herein.

RESPONSE:

Defendants incorporate and reallege its responses to Paragraphs 1 through 62 above, as if set forth in full herein.

64. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 64.

65. There is an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 65.

66. Defendants have made, and will continue to make, substantial preparation in the United States, including New Jersey, to manufacture, use, sell, offer to sell, or import the generic product upon the FDA's approval of ANDA No. 207139.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 66.

67. Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '663 patent will constitute direct, induced, and contributory infringement of said patent.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 67.

68. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '663 patent will constitute direct, induced, and contributory infringement of the '663 patent.

RESPONSE:

No response is required at this time because the allegations of this paragraph are subject to Defendants' Motion to Dismiss. To the extent a response is required, Defendants deny the allegations of Paragraph 68.

RESPONSE TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Defendants further deny that Noven is entitled to any of the relief set forth in their "Prayer for Relief" or to any other relief.

JURY DEMAND

Defendants demand trial by jury as to all issues so triable.

AFFIRMATIVE DEFENSES

Without any admission as to burden of proof and expressly reserving their right to assert any additional defenses or counterclaims that discovery may reveal, Defendants state the following defenses:

First Affirmative Defense

The manufacture, use, offer for sale or sale of the ALF ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe directly and/or indirectly, any valid and enforceable claim of the '447 patent.

Second Affirmative Defense

One or more of the claims of the '447 patent are invalid and/or unenforceable under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidation or unenforceability.

Third Affirmative Defense

The manufacture, use, offer for sale or sale of the ALF ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe directly and/or indirectly, any valid and enforceable claim of the '271 patent.

Fourth Affirmative Defense

One or more of the claims of the '271 patent are invalid and/or unenforceable under one

or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidation or unenforceability.

Fifth Affirmative Defense

The manufacture, use, offer for sale or sale of the ALF ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe directly and/or indirectly, any valid and enforceable claim of the '663 patent.

Sixth Affirmative Defense

One or more of the claims of the '663 patent are invalid and/or unenforceable under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidation or unenforceability.

Seventh Affirmative Defense

The claims against ALF, Actavis Pharma, Andrx, and Actavis fail for lack of subject matter jurisdiction.

Eighth Affirmative Defense

The Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

Ninth Affirmative Defense

Neither the filing of ANDA No. 207139 nor the defense of this action gives rise to an exceptional case under 35 U.S.C. § 285.

Tenth Affirmative Defense

Any additional defenses that discovery may reveal.

WHEREFORE, Defendants hereby demand judgment dismissing Plaintiff's Complaint with prejudice, judgment for costs and fees of suit and for such other relief as the Court may

deem just and proper.

COUNTERCLAIMS OF DEFENDANT/COUNTERCLAIM-PLAINTIFF ACTAVIS LABORATORIES FL, INC.

Without admitting any of the allegations of Plaintiff's Complaint for Patent Infringement other than those allegations expressly admitted herein, and without prejudice to Defendants' right to plead additional counterclaims as the facts of the matter warrant, Defendant/Counterclaim-Plaintiff Actavis Laboratories FL, Inc. ("ALF") brings the following Counterclaims against Plaintiff/Counterclaim-Defendant Noven Therapeutics, LLC ("Noven" or "Plaintiff") and states as follows:

NATURE OF THE ACTION

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, based on an actual controversy between ALF and Noven to declare that ALF is free to continue to seek approval of its Abbreviated New Drug Application ("ANDA") No. 207139, and upon approval by the United States Food and Drug Administration ("FDA") to engage in the manufacture, use, offer for sale, and/or sale of products described in ANDA No. 207139 (hereinafter "the ALF ANDA Product").

THE PARTIES

2. Defendant/Counterclaim-Plaintiff ALF is a corporation organized and existed under the laws of Florida with a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. On information and belief, Plaintiff/Counterclaim-Defendant Noven is a Delaware limited liability company with a principal place of business at 11960 S.W. 144th

Street, Miami, Florida 33186.

4. Noven purports to be the owner of all title, right, and interest in and to U.S. Patent Nos. 5,874,447 (the "'447 patent"), 7,598,271 (the ''271 patent"), and 8,658,663 (the ''663 patent") (collectively, the "patents-in-suit").

JURISDICTION AND VENUE

5. On October 16, 2014, Noven filed a Complaint in this Court seeking, among other things, a judgment that ALF infringed one or more claims of the patents-in-suit by filing a Paragraph IV Certification. An immediate and justiciable controversy exists between ALF, on the one hand, and Noven, on the other, regarding whether the ALF ANDA Product infringes any valid and enforceable claim of the patents-in-suit.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Personal jurisdiction is proper in this Court as to Noven, because, *inter alia*, Noven has subjected itself to the jurisdiction of this Court by virtue of filing its Complaint.

8. Because Noven has sued ALF in this District, a substantial portion of the events giving rise to these counterclaims arose in this District for purposes of 28 U.S.C. § 1391(b)(2).

FIRST COUNTERCLAIM
(Declaration of Non-Infringement of the '447 Patent)

9. ALF realleges and incorporates by reference Paragraphs 1 through 8 of these counterclaims.

10. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and seeks a declaration that the claims of the '447 patent will not be infringed by the manufacture, use, offer for sale, or sale of the ALF ANDA Product.

11. Noven asserts that the manufacture, use, offer for sale, or sale of the ALF ANDA Product will infringe claims of the ’447 patent.

12. The manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’447 patent.

13. A present, genuine and justiciable controversy exists between ALF and Noven regarding whether the manufacture, use, offer for sale, or sale of the ALF ANDA Product will infringe any valid and enforceable claim of the ’447 patent.

14. ALF is entitled to a declaration that the manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe any valid and enforceable claim of the ’447 patent.

SECOND COUNTERCLAIM
(Declaration of Invalidity of the ’447 Patent)

15. ALF incorporates by reference and realleges Paragraphs 1 through 14 of its counterclaims.

16. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and seeks a declaration that the claims of the ’447 patent are invalid.

17. Noven asserts that the claims of the ’447 patent are valid and infringed by the ALF ANDA Product.

18. The manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe the ’447 patent, because the claims of the ’447 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidation or unenforceability.

19. A present, genuine and justiciable controversy exists between ALF and Noven regarding the validity of the claims of the ’447 patent.

20. ALF is entitled to a declaration that the claims of the ’447 patent are invalid.

THIRD COUNTERCLAIM
(Declaration of Non-Infringement of the ’271 Patent)

21. ALF realleges and incorporates by reference Paragraphs 1 through 20 of these counterclaims.

22. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and seeks a declaration that the claims of the ’271 patent will not be infringed by the manufacture, use, offer for sale, or sale of the ALF ANDA Product.

23. Noven asserts that the manufacture, use, offer for sale, or sale of the ALF ANDA Product will infringe claims of the ’271 patent.

24. The manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’271 patent.

25. A present, genuine and justiciable controversy exists between ALF and Noven regarding whether the manufacture, use, offer for sale, or sale of the ALF ANDA Product will infringe any valid and enforceable claim of the ’271 patent.

26. ALF is entitled to a declaration that the manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe any valid and enforceable claim of the ’271 patent.

FOURTH COUNTERCLAIM
(Declaration of Invalidity of the ’271 Patent)

27. ALF incorporates by reference and realleges Paragraphs 1 through 26 of its

counterclaims.

28. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and seeks a declaration that the claims of the ’271 patent are invalid.

29. Noven asserts that the claims of the ’271 patent are valid and infringed by the ALF ANDA Product.

30. The manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe the ’271 patent, because the claims of the ’271 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidation or unenforceability.

31. A present, genuine and justiciable controversy exists between ALF and Noven regarding the validity of the claims of the ’271 patent.

32. ALF is entitled to a declaration that the claims of the ’271 patent are invalid.

FIFTH COUNTERCLAIM
(Declaration of Non-Infringement of the ’663 Patent)

33. ALF realleges and incorporates by reference Paragraphs 1 through 32 of these counterclaims.

34. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and seeks a declaration that the claims of the ’663 patent will not be infringed by the manufacture, use, offer for sale, or sale of the ALF ANDA Product.

35. Noven asserts that the manufacture, use, offer for sale, or sale of the ALF ANDA Product will infringe claims of the ’663 patent.

36. The manufacture, use, offer for sale, or sale of the ALF ANDA Product does not

and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '663 patent.

37. A present, genuine and justiciable controversy exists between ALF and Noven regarding whether the manufacture, use, offer for sale, or sale of the ALF ANDA Product will infringe any valid and enforceable claim of the '663 patent.

38. ALF is entitled to a declaration that the manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe any valid and enforceable claim of the '663 patent.

SIXTH COUNTERCLAIM
(Declaration of Invalidity of the '663 Patent)

39. ALF incorporates by reference and realleges Paragraphs 1 through 38 of its counterclaims.

40. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and seeks a declaration that the claims of the '663 patent are invalid.

41. Noven asserts that the claims of the '663 patent are valid and infringed by the ALF ANDA Product.

42. The manufacture, use, offer for sale, or sale of the ALF ANDA Product does not and will not infringe the '663 patent, because the claims of the '663 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidation or unenforceability.

43. A present, genuine and justiciable controversy exists between ALF and Noven regarding the validity of the claims of the '663 patent.

44. ALF is entitled to a declaration that the claims of the '663 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff ALF respectfully requests that this Court enter judgment in its favor and against Plaintiff/Counterclaim-Defendant Noven as follows:

A. dismissing the Complaint, and denying each of the claims for relief contained therein, with prejudice;

B. declaring that ALF and the ALF ANDA Product have not infringed, are not infringing and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable of the '447 patent;

C. declaring the claims of the '447 patent invalid;

D. declaring that ALF and the ALF ANDA Product have not infringed, are not infringing and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable of the '271 patent;

E. declaring the claims of the '271 patent invalid;

F. declaring that ALF and the ALF ANDA Product have not infringed, are not infringing and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable of the '663 patent;

G. declaring the claims of the '663 patent invalid;

H. declaring this an exceptional case under 35 U.S.C. § 285 and awarding ALF its attorneys' fees, costs, and expenses; and

I. granting ALF such other and further relief as this Court deems just and proper.

Dated: November 7, 2014

CONNELL FOLEY LLP

s/Liza M. Walsh

Liza M. Walsh
Rukhsanah L. Singh
85 Livingston Avenue
Roseland, NJ 07068
Phone: (973) 535-0500
Fax: (973) 535-9217

Of Counsel:
Ralph J. Gabric (*pro hac vice pending*)
Joshua E. Ney, Ph.D. (*pro hac vice pending*)
Danielle C. Gillen (*pro hac vice pending*)
David M. Hanna (*pro hac vice pending*)
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive, Suite 3600
Chicago, Illinois 60611-5599
Phone: (312) 321-4200

Attorneys for Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Andrx Corp., and Actavis Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any other court or of any pending arbitration or administration proceeding.

Dated: November 7, 2014

CONNELL FOLEY LLP

s/Liza M. Walsh

Liza M. Walsh
Rukhsanah L. Singh
85 Livingston Avenue
Roseland, NJ 07068
Phone: (973) 535-0500
Fax: (973) 535-9217

Of Counsel:
Ralph J. Gabric (*pro hac vice pending*)
Joshua E. Ney, Ph.D. (*pro hac vice pending*)
Danielle C. Gillen (*pro hac vice pending*)
David M. Hanna (*pro hac vice pending*)
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive, Suite 3600
Chicago, Illinois 60611-5599
Phone: (312) 321-4200

Attorneys for Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Andrx Corp., and Actavis Inc.